-- FOR PUBLICATION --

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

GARY A. SMITH, TAMARA SMITH h/w, Plaintiffs,	**CIVIL ACTION**
v.	
HOWMEDICA OSTEONICS CORP. AND STRYKER CORPORATION, Defendants.	**NO. 17-1174**

MEMORANDUM OPINION

In this products liability action, Gary Smith and his wife Tamara Smith ("Plaintiffs") bring strict liability, negligence, breach of implied warranty and loss of consortium claims under Pennsylvania law following the surgical implantation of the Stryker Gamma 3 Nail System into Mr. Smith's left hip and leg. Howmedica Osteonics Corp. and Stryker Corporation ("Defendants") move to dismiss the Complaint in its entirety for failure to state a claim pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure. The motion will be granted in part and denied in part.

I. Background

On March 2, 2015, Mr. Smith underwent a surgical procedure performed by Dr. Ernest E. Cope, III, at Grand View Hospital in Bucks County to implant the Stryker Gamma 3 Nail System. Defendants "designed, manufactured, assembled, distributed and sold" the prosthetic implant system, including the product used in Mr. Smith's procedure.

Mr. Smith's recovery did not go well. Although, on May 15, 2015, x-ray images "revealed a healed intertrochanteric fracture with good position of the Stryker gamma nail," on September 30, 2015, Plaintiff "reported pain in the region of the lag screw." X-ray images taken that day showed "sclerosis . . . compatible with healing," but also "revealed a broken Stryker

gamma nail." Subsequent CT scans on October 6, 2015 and January 11, 2016 appeared to show that the fracture had healed, and that the implant was in the proper position. However, a later "addendum" to the January 11, 2016 scan indicated that there was "minimal healing at the fracture site with a now chronic ununited fracture." On March 30, 2016, Dr. Paul L. Weidner informed Plaintiff that "the fracture had gone on to nonunion," and that the implanted device had "broken" or suffered a "mechanical complication." As a result, on April 26, 2016, Mr. Smith was then required to undergo a "left total hip replacement . . . after which [he] developed an infection requiring further treatment and medical consequences."

Mr. Smith alleges various physical and economic injuries stemming from the failed implantation of the Stryker Gamma 3 Nail System and subsequent total hip replacement, and Ms. Smith alleges that due to these injuries, she was deprived of the consortium of her spouse.

II. Legal Standard

"To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). "In light of *Twombly*, 'it is no longer sufficient to allege mere elements of a cause of action; instead a complaint must allege facts suggestive of [the proscribed] conduct.'" *Great W. Mining & Mineral Co. v. Fox Rothschild LLP*, 615 F.3d 159, 177 (3d Cir. 2010) (quoting *Phillips v. County of Allegheny*, 515 F.3d 224, 233 (3d Cir. 2008)).

III. Discussion

Defendants contend that Pennsylvania does not recognize strict liability or breach of implied warranty claims against manufacturers of prescription medical devices like the Stryker Gamma 3 Nail System. Additionally, they argue that Plaintiffs have failed to allege facts

sufficient to support their strict liability, negligence, and breach of implied warranty claims. Noting that Ms. Smith's loss of consortium claim is purely derivative of her husband's tort claims, Defendants seek to dismiss it as well.

A. Strict Liability - Count One

1. Existence of strict liability claim against medical device manufacturers under Pennsylvania law

To determine whether Pennsylvania law categorically exempts prescription medical devices, like the Stryker Gamma 3 Nail System, from all strict liability claims, it is necessary to begin with Pennsylvania's general approach to strict products liability.

In products liability cases, Pennsylvania follows the formulation of strict liability set out in Section 402A of the Restatement (Second) of Torts. *Webb v. Zern*, 220 A.2d 853, 854 (Pa. 1966) (adopting the language of Section 402A as the law of the Commonwealth); *see also Tincher v. Omega Flex, Inc.*, 104 A.3d 328, 394-99 (Pa. 2014) (overruling *Azzarello v. Black Bros. Co.*, 391 A.2d 1020 (Pa. 1978), and declining to adopt the formulation of strict products liability set out in the Restatement (Third) of Torts). Strict liability under Section 402A allows a plaintiff to recover where their injury was caused by a product in "a defective condition unreasonably dangerous to the user or consumer." *Phillips v. A-Best Prod. Co.*, 665 A.2d 1167, 1170-71 (Pa. 1995). A defective condition may be established by proving either a manufacturing defect, a design defect, or a failure-to-warn defect.[1] *Id.* In this case, Count One is styled as a

[1] A manufacturing defect requires proof that there was "'a breakdown in the machine or a component thereof,'" while a design defect requires proof that "'the design . . . results in an unreasonably dangerous product.'" *Barton v. Lowe's Home Ctrs., Inc.*, 124 A.3d 349, 355 (Pa. Super. Ct. 2015) (quoting *Riley v. Warren Mfg., Inc.*, 688 A.2d 221, 224 (Pa. Super. Ct. 1997)). A failure-to-warn defect stems from "the defendant's failure to provide adequate instructions to the user on how to use the product as the product was designed." *Id.* (citing *Weiner v. American Honda Motor Co., Inc.*, 718 A.2d 305, 309 (Pa. Super. Ct. 1998)).

strict liability claim asserting both a design defect and a manufacturing defect, but not a failure-to-warn defect.

At issue is Comment k to Section 402A, which creates an exception to the general rule of strict liability for "[u]navoidably unsafe products" to the extent that "[s]uch a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it *unreasonably* dangerous." Restatement (Second) of Torts, § 402A cmt. k. Where Comment k applies, its plain language bars strict liability claims that assert a design defect. *Incollingo v. Ewing*, 282 A.2d 206, 219 (Pa. 1971) (observing that Pennsylvania does not impose strict liability on prescription drugs "merely because of dangerous propensities of the product"); *see also Baldino v. Castagna*, 478 A.2d 807, 810 (Pa. 1984) ("In *Incollingo* we held that, assuming proper preparation and warning, a manufacturer of drugs is not strictly liable for unfortunate consequences attending the use of otherwise useful and desirable products which are attended with a known but apparently reasonable risk."). As to the threshold question of whether the Stryker Gamma 3 Nail System is unavoidably unsafe, Plaintiffs do not dispute that it is, and so Comment k applies. *See* Opp'n at 4-6. Therefore, Defendants' motion to dismiss Plaintiffs' strict liability claim will be granted to the extent that it asserts a design defect.

The issue that is actually disputed is whether Pennsylvania's interpretation of Comment k also forecloses Plaintiffs' strict liability claim insofar as it asserts a manufacturing defect. Comment k protection is explicitly conditioned on the product being "properly prepared," and "accompanied by proper directions and warning." Restatement (Second) of Torts, § 402A cmt. k. On its face, this language might seem to preserve strict liability claims asserting a manufacturing defect and a failure-to-warn defect, even where Comment k applies. However, with respect to the "proper directions and warning" language, the Pennsylvania Supreme Court

has interpreted it to limit recovery for failure-to-warn in Comment k cases to negligence. *Hahn v. Richter*, 673 A.2d 888, 889-91 (Pa. 1996) ("[W]here the adequacy of warnings associated with prescription drugs is at issue, the failure of the manufacturer to exercise reasonable care to warn of dangers, *i.e.*, the manufacturer's negligence, is the only recognized basis of liability."). But as relevant here, the Court has not directly interpreted the "properly prepared" language, or otherwise decided whether manufacturing defect strict liability claims may proceed where Comment k applies.

"In the absence of a controlling decision by the Pennsylvania Supreme Court, a federal court applying that state's substantive law must predict how Pennsylvania's highest court would decide this case." *Berrier v. Simplicity Mfg., Inc.*, 563 F.3d 38, 45-46 (3d Cir. 2009). "[A] federal court attempting to forecast state law must consider relevant state precedents, analogous decisions, considered dicta, scholarly works, and any other reliable data tending convincingly to show how the highest court in the state would decide the issue at hand." *McKenna v. Ortho Pharm. Corp.*, 622 F.2d 657, 663 (3d Cir. 1980). Decisions of the lower state courts can be given "due regard, but not conclusive effect," while "[t]he opinions of intermediate appellate state courts are not to be disregarded by a federal court unless it is convinced by other persuasive data that the highest court of the state would decide otherwise." *Nationwide Mut. Ins. Co. v. Buffetta*, 230 F.3d 634, 637 (3d Cir. 2000) (internal quotation marks and citations omitted).

Interpreting the "properly prepared" language to preserve manufacturing defect strict liability claims in Comment k cases would be consistent with the Pennsylvania Supreme Court's recent summary of its strict products liability jurisprudence in *Tincher v. Omega Flex, Inc.*, 104 A.3d 328 (Pa. 2014). There, the Court articulated a strong policy preference for strict liability in products liability cases, stating that "[n]o product is expressly exempt [from strict liability] and,

as a result, the presumption is that strict liability may be available with respect to any product . . . ." *Id.* at 382 (citing Restatement (Second) of Torts, § 402A cmt. b). Although the Court acknowledged the exceptions to the general rule of strict liability for products protected by Comment k, whereby design defect and failure-to-warn claims against manufacturers of unavoidably unsafe products are limited to negligence, the Court was silent regarding the viability of manufacturing defect strict liability claims under Comment k. *See id.* (citing *Hahn v. Richter*, 673 A.2d 888 (Pa. 1996)).[2] Moreover, the comprehensive and academic nature of the *Tincher* opinion suggests that the Court's failure to mention a categorical bar to all strict liability claims against medical device manufacturers was neither inadvertent, nor a stylistic choice. Instead, the omission is a strong indication that under Pennsylvania law no such bar exists.[3]

Further support for the viability of manufacturing defect strict liability claims in the Comment k context is found in *Lance v. Wyeth*, 4 A.3d 160 (Pa. Sup. Ct. 2010), *aff'd in part, rev'd in part on other grounds*, 85 A.3d 434 (Pa. 2014). There, a panel of the Pennsylvania Superior Court observed that under the Pennsylvania Supreme Court's interpretation of Comment k, the only viable basis for a strict liability claim in a Comment k case is a manufacturing defect. *See id.* at 164-65 (first citing *Baldino*, 478 A.2d at 810, for the proposition that design defect claims may not proceed in strict liability under Comment k; then

[2] It bears observation that the citation to *Hahn* in *Tincher* conflates design defect and failure-to-warn defect theories. *See* 104 A.3d at 382 (parenthetically describing *Hahn v. Richter* as holding that manufacturers of prescription drugs are "immune from strict liability defective design claim[s] premised upon [the] sale of prescription drugs without adequate warning"). Although the only theory of defect pursued in *Hahn* was the manufacturer's failure to warn, 673 A.2d 888, the least-strained reading of *Tincher*'s citation to *Hahn* is that the Court was referring to the limitation of both design and failure-to-warn defect claims to a theory of negligence in the Comment k context.

[3] To be sure, in *Tincher*, the plaintiffs asserted a design defect strict liability claim against a manufacturer of a product to which Comment k was inapplicable, 104 A.3d at 336-37, and so neither Comment k, nor its "properly prepared" language were at issue. Normally, no significance could be drawn from a court's failure to mention a rule of law not directly implicated by the facts. However, the *Tincher* court observed that although "[o]ur decision is limited to the context of a 'design defect' claim by the facts . . . the foundational principles upon which we touch may ultimately have broader implications by analogy." *Id.* at 384 n.21.

citing *Hahn v. Richter*, 673 A.2d at 90-91, for the proposition that failure-to-warn claims may only proceed in negligence where Comment k applies). And although the decision was subsequently reversed in part on unrelated grounds,[4] the opinion of the Pennsylvania Supreme Court did not address the Superior Court's discussion of the available bases for strict liability under Comment k. *See* 85 A.3d at 440 n.8 (rejecting the Superior Court's application of strict liability rules to a negligence claim).

Nevertheless, several recent district court opinions predicting Pennsylvania law have found support in the Pennsylvania Supreme Court's opinion in *Lance* for a categorical bar to all strict liability claims against medical device manufacturers. *McLaughlin v. Bayer Corp.*, 172 F. Supp. 3d 804, 833-34 (E.D. Pa. 2016) (citing 85 A.3d at 453); *Wilson v. Synthes USA Prods., LLC*, 116 F. Supp. 3d 463, 467 (E.D. Pa. 2015) (citing 85 A.3d at 453); *Terrell v. Davol, Inc.*, No. CIV.A. 13-5074, 2014 WL 3746532, at *5 (E.D. Pa. July 30, 2014) (citing 85 A.3d at 453). These opinions rely on the Court's isolated remark that "for policy reasons this Court has declined to extend strict liability into the prescription drug arena." 85 A.3d at 453. Noting that the Court did not in the same breath add any qualification with regard to manufacturing defects, these opinions infer the existence in Pennsylvania law of a categorical bar to all strict liability claims against prescription drug manufacturers, including those that assert a manufacturing defect. 172 F. Supp. 3d at 833 (citing *id.*); 116 F. Supp. 3d at 467 (citing *id.*); *Terrell*, 2014 WL 3746532, at *5 (citing *id.*). They then predict that the Pennsylvania Supreme Court would extend this putative bar to manufacturing defect strict liability claims to protect medical device

[4] In *Lance v. Wyeth* the Pennsylvania Supreme Court affirmed the Superior Court's decision that design defect claims against prescription drug manufacturers may proceed in negligence, despite Comment k's preclusion of such claims in strict liability. 85 A.3d at 451-52. It reversed the Superior Court to the extent that the lower court held that the failure to withdraw or recall the drug at issue could not also serve as a basis for a negligence claim. *Id.* at 459-60.

manufacturers as well. 172 F. Supp. 3d at 834; 116 F. Supp. 3d at 467; *Terrell*, 2014 WL 3746532, at *5.

Reading the language from *Lance* in context, this Court cannot reach the same conclusion. The Pennsylvania Supreme Court's observation that, previously, it "has declined to extend strict liability into the prescription drug arena," seems to refer to the line of Comment k cases that have limited design defect and failure-to-warn claims against prescription drug manufacturers to negligence, a discussion of which immediately precedes the remark. *See Lance*, 85 A.3d at 452 n.21, 453 (first citing *Hahn v. Richter*, 673 A.2d 889-91 (Pa. 1996); then citing *Incollingo v. Ewing*, 282 A.2d 206, 219 (Pa. 1971)). Because the Pennsylvania Supreme Court did not address manufacturing defect strict liability claims in *Hahn* or *Incollingo* – or for that matter, in any of its prior cases – its reference to *Hahn* and *Incollingo* in *Lance* cannot have been meant to imply a categorical bar to all strict liability claims against prescription drug manufacturers.

As to the prediction that, based on *Hahn*, the Pennsylvania Supreme Court would bar manufacturing defect strict liability claims against medical device manufacturers, the decisions in *McLaughlin*, *Wilson* and *Terrell* are the most recent in a line of district court opinions to reach this conclusion. *E.g.*, *Gross v. Stryker Corp.*, 858 F. Supp. 2d 466, 482 (W.D. Pa. 2012); *Soufflas v. Zimmer Inc.*, 474 F. Supp. 2d 737, 750 (E.D. Pa. 2007); *Parkinson v. Guidant Corp.*, 315 F. Supp. 2d 741, 747 (W.D. Pa. 2004); *Davenport v. Medtronic, Inc.*, 302 F. Supp. 2d 419, 422 (E.D. Pa. 2004). But as Judge Yohn first observed, "[f]ew of these courts . . . have addressed the 'properly prepared' requirement in Comment k or otherwise distinguished design defect, manufacturing defect and failure-to-warn claims . . . ." *Doughtery v. C.R. Bard, Inc.*, No. CIV.A. 11-6048, 2012 WL 2940727, at *4 (E.D. Pa. July 18, 2012) (predicting that Pennsylvania

would allow manufacturing defect strict liability claims against medical device manufacturers). Following Judge Yohn's reasoning in *Doughtery*, numerous district court opinions have predicted the Pennsylvania Supreme Court would allow a manufacturing defect based strict liability claim against medical device manufacturers. *E.g.*, *Wagner v. Kimberly–Clark Corp.*, No. CV 16-4209, 2016 WL 7079571, at *5 (E.D. Pa. Dec. 1, 2016); *Kline v. Zimmer Holdings, Inc.*, No. CIV.A. 13-513, 2013 WL 3279797, at *4-*6 (W.D. Pa. June 27, 2013); *Bergstresser v. Bristol-Myers Squibb Co.*, No. CIV.A. 3:12-1464, 2013 WL 1760525, at *3 (M.D. Pa. Apr. 24, 2013); *Tatum v. Takeda Pharm. N. Am., Inc.*, No. CIV.A. 12-1114, 2012 WL 5182895, at *2 (E.D. Pa. Oct. 19, 2012); *Killen v. Stryker Spine*, No. CIV.A. 11-1508, 2012 WL 4498865, at *3-*4 (W.D. Pa. Sept. 28, 2012).

Those opinions allowing a manufacturing defect claim to proceed in strict liability under Comment k have the better analysis. The decision in *Hahn* was limited on its facts to failure-to-warn defects, and as such, its rationale dealt solely with the treatment of failure-to-warn claims. *See* 673 A.2d at 889-91. Moreover, *Hahn*'s rationale is not obviously transferrable to the manufacturing defect context because it relied primarily on an interpretation of Comment j to Section 402A, which defines proper "directions and warnings," and also on two earlier failure-to-warn cases that do not discuss manufacturing defects. *See id.* (citing first Restatement (Second) of Torts § 402A cmt. j; then citing *Incollingo v. Ewing*, 282 A.2d 206 (Pa. 1971); then citing *Baldino v. Castagna*, 478 A.2d 807 (Pa. 1984)). Accordingly, by conflating the distinct theories of defect that may support a Section 402A strict products liability claim, those decisions that have barred manufacturing defect strict liability claims against medical device manufacturers have predicted that the Pennsylvania Supreme Court would extend *Hahn* far beyond the facts on which it arose. This outcome seems increasingly questionable, as the

Pennsylvania Supreme Court in *Lance* went out of its way to criticize *Hahn* and its progeny, noting that "the truncated analysis in the *Hahn* line offers a poor foundation for extrapolation." *Lance*, 85 A.3d at 452 n.21.

For the foregoing reasons, this Court predicts that the Pennsylvania Supreme Court would not bar strict liability claims asserting a manufacturing defect against medical device manufacturers under Comment k.

2. Sufficiency of factual allegations to support a manufacturing defect strict liability claim

Having concluded that Plaintiffs' strict liability claim may proceed insofar as it alleges a manufacturing defect, the Court turns next to Defendants' argument that the Complaint lacks sufficient factual allegations to support it. A strict liability claim generally requires proof "(1) that the product was defective, (2) that the defect existed when it left the hands of the defendant, and (3) that the defect caused the harm." *Riley v. Warren Mfg., Inc.*, 688 A.2d 221, 224 (Pa. Super. Ct. 1997). A manufacturing defect may be established by direct evidence of "a breakdown in the machine or a component thereof." *Id.* Alternately, a manufacturing defect may be established by circumstantial evidence – sometimes referred to as a "malfunction theory" – where a plaintiff can rule out abnormal use or secondary causes of a malfunction. *Rogers v. Johnson & Johnson Prods., Inc.*, 565 A.2d 751, 754 (Pa. 1989).

Here, Plaintiffs have plausibly alleged a manufacturing defect strict liability claim. The existence of a manufacturing defect is satisfied by the allegation that the Stryker Gamma 3 Nail System broke down after it was implanted into Mr. Smith, where it was subjected to normal and anticipated use, and that there were no reasonable secondary causes. That it existed at the time it left Defendants' control is plausibly suggested by the allegation that the product was manufactured and shipped by Defendants to Grand View Hospital, where it was ultimately

implanted into Mr. Smith. And causation follows from the allegation that the failure of the Stryker Gamma 3 Nail System necessitated a subsequent surgery to remove it, as well as a total hip replacement, which gave rise to a secondary infection. Therefore, the motion to dismiss the strict liability claim insofar as it asserts a manufacturing defect will be denied.

B. Negligence – Count Two

Turning next to Count Two, which Defendants contend lacks sufficient factual allegations to state a claim for negligence. "To prevail in a negligence action, a plaintiff 'must show that the defendant had a duty to conform to a certain standard of conduct, that the defendant breached that duty, that such breach caused the injury in question, and actual loss or damage.'" *Berrier v. Simplicity Mfg., Inc.*, 563 F.3d 38, 61 (3d Cir. 2009) (quoting *Phillips v. Cricket Lighters*, 841 A.2d 1000, 1008 (Pa. 2003)). In their motion, Defendants do not dispute that Plaintiffs have adequately alleged causation and the existence of damages, *see* Mot. at 11, and their passing assertion that Plaintiffs have not alleged the existence of a duty owed to Mr. Smith is without merit.[5] Accordingly, the sole issue to be resolved is whether Plaintiffs have alleged facts plausibly suggesting that Defendants breached the applicable standard of care.

To make out a breach, Plaintiffs assert the following theories: negligent manufacturing and design of the Stryker Gamma 3 Nail System, as well as negligent failure to warn and to recall. As compared with strict products liability, the Pennsylvania Supreme Court has suggested that there is less of a distinction between the treatment of claims asserting negligent manufacturing, design and failure to warn. *Lance v. Wyeth*, 85 A.3d 434, 458 (Pa. 2014) ("[I]n . . . negligence . . . the substantive allegations are more important than the labels."). This is

[5] The existence of a duty to exercise reasonable care in the manufacturing of a product is implied in the supplier-consumer relationship. *See Tincher*, 104 A.3d 328 at 382. A supplier-consumer relationship is pled in the Complaint, and therefore, Plaintiffs have adequately alleged that Defendants owed them a duty to exercise reasonable care in the manufacture of the Stryker Gamma 3 Nail System.

because in strict liability, "the focus is exclusively on the product" while in negligence, "the main focus is on conduct." *Id.*; *see also Harford Mut. Ins. Co. v. Moorhead*, 578 A.2d 492, 501 (Pa. Super. Ct. 1990) ("Pennsylvania courts consistently analyze the negligence/failure to warn and strict liability/failure to warn causes of action separately, treating conduct-related counts apart from product-related counts.").

Nevertheless, such labels are useful to the extent that they are associated with the various provisions of the Restatement (Second) of Torts that Pennsylvania follows in products liability claims in negligence. Manufacturing defects are governed by Section 395,[6] and design defects are governed by Section 398.[7] *Lance v. Wyeth*, 85 A.3d 434, 445 n.13 (Pa. 2014) ("[T]his Court has rather roundly endorsed the substantive principles reflected in both Sections 395 and 398 . . . as having been 'adopted in practically all jurisdictions.'" (quoting *Foley v. Pittsburgh–Des Moines Co.*, 68 A.2d 517, 531 (Pa. 1949)). Claims for negligent failure to warn are governed by Section 388,[8] *Incollingo v. Ewing*, 282 A.2d 206, 220 n.8 (Pa. 1971) ("Under this section, the supplier has a duty to exercise reasonable care to inform those for whose use the article is supplied of the facts which make it likely to be dangerous."), and the Pennsylvania Supreme

[6] "A manufacturer who fails to exercise reasonable care in the manufacture of a chattel which, unless carefully made, he should recognize as involving an unreasonable risk of causing physical harm to those who use it for a purpose for which the manufacturer should expect it to be used and to those whom he should expect to be endangered by its probable use, is subject to liability for physical harm caused to them by its lawful use in a manner and for a purpose for which it is supplied." Restatement (Second) of Torts § 395.

[7] "A manufacturer of a chattel made under a plan or design which makes it dangerous for the uses for which it is manufactured is subject to liability to others whom he should expect to use the chattel or to be endangered by its probable use for physical harm caused by his failure to exercise reasonable care in the adoption of a safe plan or design." Restatement (Second) of Torts § 398.

[8] "One who supplies directly or through a third person a chattel for another to use is subject to liability to those whom the supplier should expect to use the chattel with the consent of the other or to be endangered by its probable use, for physical harm caused by the use of the chattel in the manner for which and by a person for whose use it is supplied, if the supplier (a) knows or has reason to know that the chattel is or is likely to be dangerous for the use for which it is supplied, and (b) has no reason to believe that those for whose use the chattel is supplied will realize its dangerous condition, and (c) fails to exercise reasonable care to inform them of its dangerous condition or of the facts which make it likely to be dangerous." Restatement (Second) of Torts § 388.

Court has suggested that claims for negligent failure to recall may be as well, *see Lance*, 85 A.3d at 459-60 (observing that a manufacturer's duty "can be viewed [as] on a continuum" according to the known or knowable risks, potentially encompassing both the duty to provide proper warnings and the duty to recall).

A close analysis of the Complaint reveals that Plaintiffs have failed to allege facts plausibly giving rise to a negligence claim under each of these theories. First with respect to negligent manufacturing, it is necessary to allege some facts that would plausibly suggest that the manufacturer failed to exercise reasonable care during the "manufacturing process." Restatement (Second) of Torts § 395. Here, there are no factual allegations that address the manufacturing process. There is only the conclusory allegation that the manufacture of the Stryker Gamma 3 Nail System was negligent, which is precisely the type of merely conclusory statement not entitled to a presumption of truth on a motion to dismiss. *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). While Plaintiffs do incorporate the factual allegations made in support of the manufacturing defect strict liability claim – that the product broke following implantation under normal and anticipated use and in the absence of any secondary causes – these are insufficient to state a claim for negligent manufacturing under Pennsylvania law because they solely address the product, and not the Defendants' conduct. Without any factual allegation as to the nature of what went wrong during the manufacturing process, there is no plausible road to recovery for negligent manufacturing.

Next, with respect to the alleged negligent design of the Stryker Gamma 3 Nail System, the factual allegations are similarly insufficient to survive a motion to dismiss. The only explicit reference to the product's design is the conclusory allegation that Defendants were negligent in such design. Setting this conclusory statement aside, the remaining factual allegations do not

address the design of the Stryker Gamma 3 Nail System in any level of meaningful detail. All that can be gleaned from the Complaint is that the product is a type of "prosthetic implant system" that is implanted into a patient's leg and hip. From this information, even accepting as true Plaintiffs' allegation that the product broke after implantation, it cannot be plausibly inferred that Defendants failed "to exercise reasonable care in the adoption of a safe . . . design" as required by Section 398.

Finally, the Complaint is equally lacking in any factual specificity with regard to the allegation that Defendants were negligent in their failure to warn or to recall. In particular, the Pennsylvania Supreme Court's formulation of negligent failure to warn and failure to recall claims in *Lance v. Wyeth* emphasized that these requirements are only imposed on manufacturers where they have actual knowledge – or should, with the exercise of reasonable care, have had actual knowledge – of the existence of unreasonable, nonobvious risks from their products. *See* 85 A.3d 434 at 459-60; *see also* Restatement (Second) of Torts § 388 (imposing duty to warn as to dangers that are known or should reasonably be known)). Here, the Complaint fails to specify what risks were known or reasonably should have been known that would have given rise to a duty to warn or to recall. Without any such allegation, Plaintiffs have failed to allege facts plausibly suggesting an entitlement to relief under either theory of negligence.

Accordingly, because Plaintiffs have failed to support their negligence claim with sufficient factual allegations, Defendants' motion to dismiss it will be granted.

C. Breach of Implied Warranty of Merchantability – Count Three

With respect to Count Three, Defendants contend that Pennsylvania does not recognize a claim for breach of the implied warranty of merchantability against medical device

manufacturers, or in the alternative, that the Complaint does not include sufficient factual allegations to support such a claim.

As to whether Plaintiffs' claim is cognizable, by statute Pennsylvania implies a warranty of merchantability in a contract for the sale of goods if the seller is "a merchant with respect to the goods of that kind." 13 Pa. Cons. Stat. § 2314(a). Such warranty requires that the goods in question be "fit for the ordinary purposes for which such goods are used." 13 Pa. Cons. Stat. § 2314(b)(3); *Gall ex rel. Gall v. Allegheny Cty. Health Dep't*, 555 A.2d 786, 789-90 (Pa. Super. Ct. 1989) ("[M]erchantability does not require that the goods be the best quality . . . or the best obtainable . . . but it does require that they have an inherent soundness which makes them suitable for the purpose for which they are designed . . . that they be free from significant defects, that they perform in the way that goods of that kind should perform . . . and that they be of reasonable quality within expected variations and for the ordinary purpose for which they are used." (citations omitted)).

Defendants do not dispute that they are merchants in goods of the kind relevant here. Instead, they argue that in Pennsylvania the rule of strict products liability and the implied warranty of merchantability are coextensive, and that because Plaintiffs' strict liability claim is not cognizable, neither is their claim for breach of the implied warranty of merchantability.

The Third Circuit has endorsed the general understanding that the implied warranty of merchantability and the rule of strict products liability in the Restatement (Second) of Torts § 402A are "essentially the same." *Gumbs v. Int'l Harvester, Inc.*, 718 F.2d 88, 94 (3d Cir. 1983) (citations omitted) (interpreting the identical provision at Section 2-314 of the Uniform Commercial Code); *see also Reese v. Ford Motor Co.*, 499 Fed. App'x 163 (3d Cir. 2012) (citing *Gumbs*, 718 F.2d at 94) (reaching the same conclusion with respect to 13 Pa. Cons. Stat. § 2314).

Applying this principle here requires the Court to recognize Plaintiffs' warranty claim to the same extent as their strict liability claim. *Doughtery*, 2012 WL 2940727, at *7. Having concluded that Plaintiffs' design defect strict liability claim is not cognizable under Comment k, Defendants' motion to dismiss will be granted to the extent that the claim for breach of the implied warranty of merchantability asserts a design defect. But having predicted that the Pennsylvania Supreme Court would recognize Plaintiffs' manufacturing defect strict liability claim, and having concluded that Plaintiffs have pled sufficient facts to support it, the motion to dismiss Count Three will be denied insofar as the breach of the implied warranty of merchantability claim asserts a manufacturing defect.[9]

D. Loss of Consortium – Count Four

Defendants' sole argument as to Ms. Smith's claim for loss of consortium in Count Four is that it is purely derivative of Mr. Smith's tort claims, and thus must be dismissed if all of his claims are dismissed. Because the Court has not dismissed all of Mr. Smith's tort claims, and given the limitations of Defendants' argument, their motion to dismiss Ms. Smith's loss of consortium claim will be denied.

An appropriate order follows.

Dated: April 27, 2017.

BY THE COURT:

/s/Wendy Beetlestone, J.

WENDY BEETLESTONE, J.

[9] The district court opinions that Defendants rely on are inapposite – they predicted the Pennsylvania Supreme Court would bar all strict liability claims against medical device manufacturers, a conclusion that this Court has rejected. *See* Mot. at 6-7 (citing *Gross v. Stryker Corp.*, 858 F. Supp. 2d 466, 491 n.34 (W.D. Pa. 2012); *Soufflas v. Zimmer, Inc.*, 474 F. Supp. 2d 737, 752 (E.D. Pa. 2007)).